

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

DORSEY & WHITNEY LLP
Attn. Abelev, Gary
250 Park Avenue
New York NY 10177
UNITED STATES OF AMERICA

Patent Mail Received

MAR 29 2006

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year)

23/03/2006

Applicant's or agent's file reference

185906/PCT 475387-164

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US2005/042408

International filing date
(day/month/year)

21/11/2005

Applicant

THE GENERAL HOSPITAL CORPORATION

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's Guide, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Chrissanthi Chouloulidou

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 185906/PCT	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2005/042408	International filing date (day/month/year) 21/11/2005	(Earliest) Priority Date (day/month/year) 24/11/2004
Applicant THE GENERAL HOSPITAL CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box No. II)

3. ☐ Unity of invention is lacking (see Box No. III)

4. With regard to the title,

- ☐ the text is approved as submitted by the applicant
☒ the text has been established by this Authority to read as follows:

COMMON-PATH INTERFEROMETER FOR ENDOSCOPIC OCT

5. With regard to the abstract,

- ☐ the text is approved as submitted by the applicant
☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 4
☐ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☒ as selected by this Authority, because this figure better characterizes the invention
- b. ☐ none of the figures is to be published with the abstract

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

Conventional endoscopic OCT suffers from a decreased signal to noise ratio because the separated measuring and reference pathes are affected by

different influences. The present invention overcomes these problems by substantially combining the reference path and the measuring path into the

same optical fibre arranged in the catheter of an endoscope. The distal optics of the endoscope includes a beam splitter for splitting the incoming light beam into a measuring path directed towards a sample and a reference path directed towards a reflector. Means may be provided to alter the length of the reference path with respect to the measuring path by translating the reflector in the reference path or changing the refractive index of the reference path. Light from the reference path and from the measuring path is brought to interference by the same beam splitter and directed to a detector through the optical fibre.

A. CLASSIFICATION OF SUBJECT MATTER
 INV. G01B9/02 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B G01B G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, INSPEC, COMPENDEX, IBM-TDB

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/057266 A (CARL ZEISS; CARL-ZEISS-STIFTUNG TRADING AS CARL ZEISS; HAUGER, CHRISTO) 8 July 2004 (2004-07-08)	1-9, 13, 15-26, 28, 30-39, 41, 42, 45-57
Y	page 10, line 15 - page 25, line 25	11, 14, 29, 40
A	figures 1-7, 13-19	10, 12, 27, 43, 44
	----- -/-	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

13 March 2006

Date of mailing of the international search report

23/03/2006

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Kunz, L

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/084263 A (MEDIZINISCHES LASERZENTRUM LUEBECK GMBH; KOCH, PETER; WOSNITZA, MARTIN) 24 October 2002 (2002-10-24)	1-8, 13-26, 28-39, 45-49, 51-56
Y	page 10, line 1 - page 17, line 31 figures 1-10	11,14, 29,40
A		9,10,12, 27, 41-44, 50,57
Y	----- US 6 341 036 B1 (TEARNEY GUILLERMO J ET AL) 22 January 2002 (2002-01-22) column 2, line 24 - column 3, line 42 figure 3	11,40
X,P	----- DE 103 51 319 A1 (MEDIZINISCHES LASERZENTRUM LUEBECK GMBH) ✓ 16 June 2005 (2005-06-16)	1-8,13, 15-26, 28, 30-37, 45-49, 51-55
	paragraph [0022] - paragraph [0041] figure 1 claim 1 -----	

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
WO 2004057266	A	08-07-2004	AU	2003290103 A1		14-07-2004
			DE	10260256 A1		15-07-2004
			DE	10392656 D2		22-12-2005
WO 02084263	A	24-10-2002	DE	10118760 A1		31-10-2002
			EP	1379857 A1		14-01-2004
			US	2004150829 A1		05-08-2004
US 6341036	B1	22-01-2002	US	2002122246 A1		05-09-2002
DE 10351319	A1	16-06-2005	NONE			

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2005/042408

International filing date (day/month/year)
21.11.2005

Priority date (day/month/year)
24.11.2004

International Patent Classification (IPC) or both national classification and IPC
INV. G01B9/02 A61B5/00

Applicant
THE GENERAL HOSPITAL CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80258 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Kunz, L

Telephone No. +49 89 2399-2628



Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- ☐ the entire international application
- ☒ claims Nos. 2-16,19-57

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☒ the claims, or said claims Nos. 2-16,19-57 are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

see separate sheet

- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13^{ter}.1(a) or (b).
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/042408

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-57
Inventive step (IS)	Yes: Claims	
	No: Claims	1-57
Industrial applicability (IA)	Yes: Claims	
	No: Claims	1-57

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

The following document (D) is referred to in this Written Opinion of the International Searching Authority:

D1 : WO 2004 / 057 266 A2

1. Objections under Article 6 PCT (Clarity)

1.1 The variations in wording between independent claims 1, 19, 32 and 37 as well as between the alternatives claimed in independent claims 1, 19 and 37 are such that the number of claims is not reasonable in consideration with the nature of the invention (Rule 6.1 (a) PCT). Furthermore, by giving seven different definitions for the same invention, the subject matter for which protection is sought is not clearly defined by the claims, contrary to the requirements of Article 6 PCT. Therefore, a statement concerning the requirements of Article 33 PCT is given only for the first claimed invention.

1.2 The claims are drafted in so vague terms and on such a level of abstraction that they are not clear in the light of the description and lack support by the description (Article 6 PCT).

The description concerns OCT interferometry for endoscopes (see pages 1 to 3, and figure 2). The goal of the invention is the provision of an interferometer where reference and sample arms traverse substantially the same path (see page 3, lines 31 to 33), in order to obviate problems associated with conventional fibre optic OCT probes (see page 3, lines 6 to 28). This goal is achieved by providing the beam splitter of the interferometer in the distal end of the endoscope, such that the "reference arm" becomes placed within the body of the catheter (see page 7, lines 5 to 16, and figures 3 and 4).

Independent claim 1, for example, is in its second embodiment drafted in so vague terms that its subject matter is anticipated by a bathroom including a mirror. Such a bathroom is namely an arrangement adapted to propagate at least one electro-magnetic radiation (light), comprising: a probe housing (the bathroom itself) and a section which is at least partially situated in the probe housing (area in front of the mirror) and configured to receive a first portion of the at least one electro-magnetic

radiation from a sample (e.g. person in front of the mirror) and a second portion of the at least one electro-magnetic radiation from a reference (mirror), wherein the first and second portions travel along substantially the same path (between the person and the mirror).

Such a level of abstraction of the claims is not appropriate and does not allow a positive statement as concerns the requirements of Article 33 PCT.

- 1.3 Claims 2 to 16 refer to the features of the second embodiment "defined" in independent claim 1. Therefore, these claims have to be excluded from the statement concerning the requirements of Article 33 PCT, which is given only for the first claimed invention.

2. Statement Concerning the Requirements of Article 33 PCT

- 2.1 Document D1 (see in particular page 10, line 1, to page 17, line 31, and figures 1, 2 and 5) describes an arrangement (36, 36a) adapted to propagate at least one electro-magnetic radiation (light from laser 43, 43a), comprising: a probe housing (36 in figure 1) and an interferometer (see figures 2 and 5) situated within the probe housing (36, 36a).

For these reasons, the subject matter of independent claim 1 is anticipated by document D1 and thus not new.

- 2.2 The features of claims 17 and 18 are also known from document D1 and thus do not add novel subject matter to the device defined in independent claim 1.
Claim 17: the interferometer shown in figures 2 and 5 is a Michelson interferometer;
Claim 18: the interferometer includes a section (I_1) configured to receive a first portion of the at least one electro-magnetic radiation from a sample (9) and a second portion of the at least one electro-magnetic radiation from a reference (surface 53, 53a), wherein the first and the second portions travel along substantially the same path (except for I_2).
- 2.3 The subject matter of the first claimed invention is also anticipated by DE-A-103 51 319, which is, however, a state of the art according to Rule 64.3 PCT.